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## Reducing Unlawful Prescription Drug Promotion: Is the Public Health Being Served by an Enforcement Approach that Focuses on Punishment?

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# FOOD *and* DRUG POLICY FORUM

REDUCING UNLAWFUL  
PRESCRIPTION DRUG PROMOTION:

*Is the Public Health Being Served by an Enforcement  
Approach that Focuses on Punishment?*

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# Reducing Unlawful Prescription Drug Promotion:

## *Is the Public Health Being Served by an Enforcement Approach that Focuses on Punishment?*

### I. INTRODUCTION

Despite the imposition of increasingly substantial fines<sup>1</sup> and recently successful efforts to impose individual liability on corporate executives under the *Park* doctrine,<sup>2</sup> punishing pharmaceutical companies and their executives for unlawful promotional activities has not been as successful in achieving compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) as the protection of the public health demands. Over the past decade, the Food and Drug Administration (FDA) and the Department of Justice (DOJ) have shifted their focus from correction and compliance to a more punitive model when it comes to allegedly unlawful promotion of pharmaceuticals. The shift initially focused on imposing monetary penalties and was arguably justified by the expectation that financial punishment would achieve a level of compliance that would reduce the need for correction. By exacting enormous fines from companies, the agencies presumably hoped that the costs associated with unlawful promotion would be too high to justify the monetary benefits of non-compliance. Unfortunately, however, that approach has not been entirely successful. Despite the growth in settlements and penalties, and the recent efforts to hold individual executives liable for corporate misbehavior, the intended impact of substantially increased compliance has only partially materialized. The upward spiraling of settlement amounts and the trend toward prosecuting repeat offenders indicate that a change in approach is necessary.

This article argues that FDA and DOJ cannot justify a continued emphasis on punishment without more demonstrable improvement in compliance and corporate accountability. The article goes on to describe several proposals to refocus the agencies' efforts to effectively address the impact of unlawful promotion on public health by returning to an approach that emphasizes the more traditional goals of correction and compliance. It also argues that any meaningful protection of the public health ultimately requires a broader public understanding of the issues surrounding unlawful promotion of pharmaceutical products and greater participation by patients; physicians; health care professionals; and others with an interest in, and the opportunity to, impact this area. Increasing the public's ability and interest in monitoring companies' promotional activities at every level will reinforce the benefits of compliance, which will better serve the public health goals of the FD&C Act.

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## POLICY RECOMMENDATIONS

- FDA should partner with companies to efficiently and effectively clarify the rules regarding off-label promotion and address their First Amendment concerns in a comprehensive fashion through informal rulemaking or substantive guidance.
- FDA should receive a portion of the fines recovered from settlements associated with unlawful drug promotion to improve and increase the agency's oversight of companies' promotion and advertising activities through its traditional correction and compliance approach.
- FDA and other entities should continue efforts to educate health care professionals, patients, and the public about lawful methods of promotion and advertising so these groups can play an active role in reducing companies' incentives to over-promote their products.

## II. BACKGROUND

The FD&C Act limits drugs sold in the United States to those that are proven to be “safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling.”<sup>3</sup> When FDA approves an application for a new drug, it identifies the specific uses for which the drug may be marketed.<sup>4</sup> Thus, promoting an approved drug for an unapproved use (i.e., for an “off-label” use) renders the drug “new” under the FD&C Act. Whether the expanded claims for use are truthful representations about a prescription drug is irrelevant, as such claims must still be approved by FDA before the manufacturer can promote them.<sup>5</sup>

Although manufacturers are generally prohibited from promoting off-label uses of their approved drugs, discussion about off-label uses among non-company parties is critical to the public health. More than half of all uses of drugs and biologics in cancer care in the United States are off-label.<sup>6</sup> The percentage of off-label uses is even higher for products used to treat pediatric patients.<sup>7</sup> Thus, FDA does not regulate the exchange of information about off-label uses between scientists, physicians, consumers, and other entities or individuals unrelated to the company to exchange and disseminate information about off-label uses.<sup>8</sup> And because off-label information is so critical to the public health, even for companies and others who are responsible for marketing an approved drug, FDA has carved out some limited exceptions to the prohibition on off-label communications.<sup>9</sup> Those exceptions reflect FDA's efforts to balance the value of exchanging off-label information against the risk of unlawful promotion; they carefully circumscribe the conditions under which the information is delivered to ensure that it is scientifically valid and not presented in a promotional manner.<sup>10</sup>

Until fairly recently, FDA bore almost sole responsibility for preventing unlawful promotion of prescription drugs through its application and enforcement of administrative, civil, and criminal penalties under the FD&C Act. As a general principle, FDA's practice has been to avoid punitive sanctions<sup>11</sup> and focus its efforts on correction and compliance.<sup>12</sup> In practice, FDA's approach resulted in the agency addressing claims on an individual basis, focusing on specific pieces of labeling, advertisements, or activities, rather than considering the overall context and collective impact of claims made as part of companies' broader marketing schemes.<sup>13</sup>

More recently, however, FDA's correction and compliance approach has been overshadowed by the DOJ's efforts to punish unlawful promotion by using enforcement tools traditionally applied in healthcare anti-fraud actions. For just over a decade now, DOJ has been pursuing a more aggressive application of the new drug and criminal misbranding provisions of the FD&C Act and has expanded its efforts to punish unlawful promotion through the False Claims Act.<sup>14</sup> Under the False Claims Act, companies that unlawfully promote approved products are treated by DOJ as the "but for" cause of physicians' decisions to prescribe those drugs and thus for the submission of a "false claim" (i.e., requesting federal health care program reimbursement for an uncovered off-label use) to the government.<sup>15</sup>

Despite the financial toll that DOJ has been able to exact from companies that engage in unlawful promotional activities, some of the companies that have previously settled with the government for significant amounts have come under repeated scrutiny for unlawful promotion violations.<sup>16</sup> Even if the focus of these subsequent enforcement actions is on behavior from a number of years ago, it does not change the perception (and in some cases the reality) that large monetary penalties alone are not achieving the anticipated levels of compliance. Indeed, Congress has expressed concerns about the limits of financial punishment and has questioned FDA and DOJ regarding the lack of enforcement actions aimed at individuals. In response, FDA and DOJ have indicated their intent to expand enforcement efforts against unlawful promotion to include more individual company executives<sup>17</sup> primarily through a revival of the responsible corporate officer doctrine (also known as the *Park* doctrine).<sup>18</sup>

Under the *Park* doctrine, the government can seek a misdemeanor conviction against a company official for violating a provision of the FD&C Act that impacts the public health (even if the official was unaware of the violation) if the official was in a position of authority to correct or prevent the violation and failed to do so.<sup>19</sup> A collateral consequence of such liability includes potential exclusion from participation in any federal health care programs under the Social Security Act,<sup>20</sup> which essentially deprives an individual of the opportunity to work in the health care industry for a prescribed period of time. Although financial penalties alone have not curtailed unlawful promotional practices, the principle under *Park* that a person may be convicted of a criminal offense even in the absence of "the conventional requirement for criminal conduct—awareness of some wrongdoing"<sup>21</sup> has been questioned on due process and fundamental fairness grounds.<sup>22</sup> Just a few months ago, however, the government's authority to impose *Park* liability was affirmed by the United State Court of Appeals for the District of Columbia when it upheld application of the exclusionary sanction imposed on several executives of the Purdue-Frederick Company.<sup>23</sup> Based on the executives' agreement to plead guilty to misdemeanor liability under *Park*, they were barred



under the Social Security Act from doing business with the federal government for 12 years.<sup>24</sup> Although the court remanded the case on the issue of the appropriate length of the debarment, it upheld the application of the sanction under *Park*.

There is no question that for many of the stakeholders interested in this issue, the threat of punishment to curtail promotional activities feels broken. In part, that is because the enforcement approach selected to address promotional activity implicates companies' First Amendment rights. Once DOJ initiates a fraud prosecution, the "unlawful" promotion that comes under review includes not only the obvious false and misleading activities of a company but also activity that arguably falls under legitimate off-label promotion and into the gray area of truthful and scientific information. Given the important role that off-label information can play in making well-informed and effective health care choices, relying primarily on a broad punishment model that diminishes the focus on the delicate balance between lawful and unlawful off-label and other types of promotion will not be the best public health choice in many cases. Moreover, to the extent punishment under DOJ's current enforcement approach moves slowly, the potential for risk to the public health increases. Reinvigorating FDA's traditional approach of encouraging correction and compliance provides a more effective choice for achieving the goals under the FDA&C Act of promoting and protecting the public health.

### III. MAJOR ISSUES IN DISPUTE

#### A. The current approach to punishing unlawful promotion fails to address pharmaceutical companies' First Amendment rights or to provide sufficient notice to companies about the boundaries for acceptable promotional speech.

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Companies that intentionally engage in promotion that is false, lacking in fair balance (i.e., between the drug's risks and benefits), or otherwise misleading<sup>25</sup> are properly punishable under the FD&C Act. Promotion and protection of the public health demands that we not tolerate false or misleading promotional claims, whether about on-label or off-label uses. Failure to curtail such unlawful promotion undercuts FDA's mandate to ensure that approved drugs are safe and effective for their intended uses and exposes patients to unnecessary and dangerous risks.

Where, however, promotion about an off-label or any other use or claim about an approved product is not false, misleading, or otherwise unlawful on its face, a policy that prevents the manufacturer of the product from communicating information about its use implicates free speech concerns under the First Amendment.<sup>26</sup> Companies have long bemoaned the lack of specific guidelines for resolving this tension between FDA regulations prohibiting the promotion of off-label uses, and their First Amendment rights to disseminate truthful scientific information about beneficial use of their products. Thus, while not a new issue, the uncertainty that still exists regarding the application of the First Amendment to speech about approved products is an important part of any conversation about the appropriate enforcement approach.

As described above, the shift over the past decade from FDA's compliance and correction approach to the DOJ's focus on punishment has significantly increased a company's risk that promotional activity will be deemed unlawful. As a result, companies are even more aware of the delicate balance they must strike between acceptable off-label promotion and that which may attract the government's attention. However, even for companies that are highly motivated to comply with promotional boundaries, it is not always possible to predict when FDA or DOJ will decide that communications about scientific and truthful information cross the First Amendment line and become "unlawful promotion." The dire consequences of this lack of guidance are evident in multiple examples over the past few years of companies' more aggressive attempts to seek guidance in this area. These efforts include individual law suits filed against FDA claiming that the agency's prohibition of off-label communications denies a company its First Amendment right to provide truthful information about lawfully marketed products.<sup>27</sup> Other companies have joined forces to request greater clarity on when promotional speech by a manufacturer is considered unlawful. In July of 2011, for example, seven companies filed a Citizen Petition requesting that FDA clarify its policies and regulations on off-label promotion of approved products.<sup>28</sup> In August 2011, the Medical Information Working Group (comprised of eleven major manufacturers of prescription drugs and medical devices) submitted an amicus brief to the United States Court of Appeals for the Second Circuit detailing the lack of clarity under current FDA regulations regarding permissible and impermissible speech and arguing that FDA restrictions in this area be subjected to heightened scrutiny.<sup>29</sup>

Although even the most detailed guidance cannot guarantee one hundred percent compliance, clearer rules would represent a substantial step forward in this area. The vast majority of companies with rigorous regulatory affairs professionals and marketing departments strive to promote products within the confines of the law; a better sense of where the First Amendment line falls would be a substantial step toward more comprehensive compliance, which in turn would benefit the public health.

**B. FDA's traditional approach to unlawful promotion, which focuses on correction and compliance, is critical to achieving the FD&C Act goals of protecting and promoting the public health and should not be subsumed by enforcement efforts that focus on punishment.**

Unlawful promotion that entails false and misleading information in any form is a serious violation of the public trust and welfare. Where, however, unlawful promotion arguably includes speech protected under the First Amendment, FDA should avoid controlling that speech in a manner that unnecessarily undermines the public health goals of the FD&C Act. Indeed, the truthful exchange of scientific information should be encouraged.

Enforcement efforts by DOJ and FDA over the past decade have relied primarily on the imposition of large financial penalties and punishment of company executives to deter future misconduct. Such efforts lack several important advantages of FDA's more traditional correction and compliance approach, including: (1) fostering collaboration between FDA and companies, (2) leveraging FDA's expertise, and (3) achieving more immediate and forward-looking results. To the extent enforcement

efforts focused primarily on punishment do not provide similar advantages, continued support of FDA's traditional approach is necessary to achieve the goals of the FD&C Act.

FDA's traditional approach to unlawful promotion fosters collaboration and communication with regulated companies. When FDA acts as the primary gate keeper, it makes a preliminary assessment as to the lawfulness of certain promotional material. Typically, FDA initiates action with a regulatory compliance (untitled or warning) letter. The letter states FDA's objection to specific claims being made in the promotional labeling or advertising and provides an opportunity for the company to discuss appropriate marketing messages with FDA. In most cases, companies comply with the agency's recommendations and reach some mutually-agreeable resolution with FDA.<sup>30</sup> Only if the parties are unable to agree is more formal action sought through FDA's Office of Chief Counsel or DOJ's Office of Consumer Litigation.

This traditional approach also effectively leverages the agency's expertise. As the gatekeeper, FDA does more than decide what companies can say about their products; it also considers important public health interests and First Amendment concerns. FDA has long recognized that balancing these competing interests is critical to preserving the important benefits associated with the free exchange of scientific information on which many health care providers and patients rely.<sup>31</sup>

Consistent with its congressionally-mandated mission to promote and protect the public health, when FDA considers the substantive content and impact of promotional labeling and advertising, its primary goal is to ensure that information is not false or misleading. In contrast, under DOJ's False Claims Act theory, even truthful off-label marketing may give rise to a "false" claim.<sup>32</sup> Thus, unlike FDA's traditional correction and compliance approach, the DOJ's use of health care fraud enforcement tools to challenge and punish unlawful promotional activity does not leverage regulatory expertise in the same way.<sup>33</sup>

Finally, when its efforts are focused on correction and compliance, FDA can effect change in a timely and productive manner. Although DOJ may obtain correction and compliance measures in a negotiated settlement,<sup>34</sup> it can take years of investigation and negotiation with companies before such measures are in place. In contrast, FDA's traditional approach has the advantage of providing timelier challenges to, and resolutions of, companies' promotional activities.

Overall, the shift from compliance to punishment has come at the cost of collaboration, subtlety, flexibility, and speed in assessing the impact of individual company communications. The cost is greatest regarding the dissemination of information that is arguably protected under the First Amendment. Thus, even if the current trend of punishing unlawful promotion beyond FDA's available administrative remedies is effective, FDA's traditional method better promotes and protects the public health and deserves continued support.

**C. The promotion and protection of the public health would be better served if the primary consumers of product information were better informed about how to evaluate it and could assume a more active role in monitoring and maintaining the quality of such information.**

There is a continuing perception that DOJ's approach—now more than a decade old—has simply been accepted by industry as part of the “cost of doing business.”<sup>35</sup> Although punishment for unlawful promotion has forced some companies to fundamentally restructure the sale and marketing of their products to discourage future violations,<sup>36</sup> reports of ongoing investigations and companies with subsequent settlement agreements continue. Additionally, DOJ's increased attention on unlawful promotion in the medical device area<sup>37</sup> also suggests that continued concern about the impact of unlawful promotion on the public health is justified. Thus, recent indicators of company compliance support the assertion that to some extent, and despite enormous financial settlements, such activity is still profitable enough to justify the risk of legal action.<sup>38</sup>

It may be that increasing the responsibility of corporate executives and Boards of Directors, through the use of the *Park* doctrine or otherwise, will eventually effectuate a change in corporate culture that will improve compliance. Even then, however, there are simply too many avenues and too many individuals involved in the sale and marketing of products to ensure total compliance. Indeed, the decision to allow direct-to-consumer advertising, which has increased dramatically since the late 1990s,<sup>39</sup> has resulted in pharmaceuticals and other health care products becoming the subject of mass marketing campaigns that span virtually every type of media outlet. If the proliferation of information was intended to result in better educated and savvier consumers of health care information, the reality is the opposite. Even physicians find it difficult to absorb all the relevant details about products.<sup>40</sup>

If direct-to-consumer and the myriad of other promotional avenues are going to remain open to companies, then all consumers of such information should be better educated about how to evaluate and monitor promotional materials that may exaggerate the safety and effectiveness of products. Even more critical for the public health, some mechanism for reporting and sharing information about unlawful promotional activities should exist.

## **IV. RESEARCH AND RESPONSE**

These specific recommendations relate to the problem areas identified in Part III.

**A. FDA should partner with companies to efficiently and effectively clarify the rules regarding off-label promotion and address their First Amendment concerns in a comprehensive fashion through informal rulemaking or substantive guidance.**

Despite years of effort, pharmaceutical companies have been unable to obtain appropriate guidance or clear answers from FDA regarding the line between truthful dissemination of scientific information and unlawful off-label promotion. As the consequences of unlawful promotion increase,

companies are asserting more pressure on FDA to draw that line in a manner consistent with the exercise of companies' First Amendment rights. FDA needs to accept its responsibility to establish clear guidelines and respond in a timely and comprehensive manner to that reasonable demand. If FDA fails to act, the agency and companies will be left with the far less attractive alternative of continued reliance on individual cases to "incrementally address[ing] discrete aspects of the government's off-label promotional policy."<sup>41</sup> Operating under that piecemeal approach serves only to reinforce companies' perceptions that they are subject to arbitrary decisions regarding the bounds of unlawful promotion, which make prediction, and thus compliance, impossible. Without creating a more compliance-focused approach, the negative consequences of unlawful promotion to physicians and patients will continue. In turn, the lack of clarity regarding compliance stifles companies' ability to disseminate *lawfully* scientific and truthful information relevant to important and developing health care concerns.

Expertise and experience make FDA especially well-equipped to shoulder the responsibility of generating promotional guidelines consistent with companies' First Amendment rights. The actual form of such guidelines is not as critical as the need to compile and articulate a comprehensive set of rules for companies to follow. Informal rulemaking or guidance documents could be as helpful as formal rulemaking. FDA's recent draft guidance to industry on responding to unsolicited requests for off-label uses<sup>42</sup> is just one example of the agency's ability to provide clear distinctions between the dissemination of truthful and scientific information and unlawful promotional behavior. Among the more helpful features of this form of guidance are examples of common factual scenarios that arise in the ordinary course of business that specifically address the types of questions companies struggle with in their efforts to market lawfully.

Indications are that FDA is motivated to develop more of these types of documents in response to industry demands for clarification. The agency's recent request for information and comments on "Communication and Activities Related to Off-Label Uses of Marketed Products and Use of Products Not Yet Legally Marketed,"<sup>43</sup> generated partly in response to the Citizen Petition,<sup>44</sup> exemplifies a natural vehicle for FDA to efficiently and effectively establish the types of detailed guidelines needed for specific types of communications. The challenge then is to push FDA to produce such documents in a timely manner.

FDA might also consider the United Kingdom's "Code of Practice for the Pharmaceutical Industry."<sup>45</sup> The broad spectrum of claims and activities covered by the Code supports the argument that it is indeed possible to establish clear guidelines about dissemination of truthful information. Moreover, the Code's inclusion of detailed supplementary information for each of its rules effectively addresses specific circumstances in a manner that encourages companies to focus on compliance. Such an approach is consistent with the Code's repeated emphasis on the promotion of the public health, which applies equally to the goals of the FD&C Act. "The Code recognizes and seeks to achieve a balance between the needs of patients, health professionals and the public, bearing in mind the political and social environment within which the industry operates and the statutory controls governing medicines."<sup>46</sup>

As illustrated by recent progress and the availability of additional resources, articulating specific guidelines is not an impossible task and no basis for further delay is justified. To the extent companies continue to pressure FDA to produce guidance documents across those areas that implicate First Amendment rights, the goals of compliance and promotion and protection of the public health will be well-served.

**B. FDA should receive a portion of the fines recovered from settlements associated with unlawful drug promotion to improve and increase the agency's oversight of companies' promotion and advertising activities through its traditional correction and compliance approach.**

FDA's traditional approach of correction and compliance allows the agency to proceed thoughtfully about individual communications and circumstances, but this approach is labor intensive. Striving to ensure that promotional labeling and advertising information is not false, lacking in fair balance (i.e., as between the drug's risks and benefits), or otherwise misleading demands medical, scientific, practical, and regulatory expertise, which is expensive. To satisfy the FD&C Act goals of promoting and protecting the public health, FDA requires substantially more resources to address and monitor companies' promotional activities, which play an important role in the delivery of healthcare information.

As described above, continuing timely collaboration between FDA and companies and leveraging FDA's expertise in this area are critical to fostering an environment of correction and compliance that will best serve the public health goals of the FD&C Act. Although suggesting an increase in funding of any agency may be politically unpopular, it seems less likely to be true in the case of FDA, which is traditionally recognized as being dangerously underfunded.<sup>47</sup> Additionally, there is a large source of funding to which FDA arguably has a special claim: fines recovered from companies for health care violations under the FD&C Act and the False Claims Act.

Currently, the large financial settlements related to unlawful promotion and recovered from pharmaceutical companies are deposited directly into the general government coffers. Thus, even while FDA testifies before Congress about the need to reauthorize the Prescription Drug and Medical Device User Fee Acts, at a cost of hundreds of millions,<sup>48</sup> companies that are directly subject to FDA oversight contribute billions of dollars in negotiated settlements to the federal government. Dedicating even a small fraction of those settlement amounts to increasing FDA oversight and compliance efforts would enhance the agency's ability to address questions and concerns about off-label and other promotional activities. Use of recovered monies for those purposes would more appropriately further the goals of protecting and promoting the public health.

**C. FDA and other entities should continue efforts to educate health care professionals, patients, and the public about lawful methods of promotion and advertising so these groups can play an active role in reducing companies' incentives to over-promote their products.**

The escalation of monetary settlements and the more recent focus on holding individuals liable for unlawful promotional activity are indicative of the government's efforts to increase accountability and change the way companies operate. In theory, there is some point at which the potential costs of unlawful promotion, whether financial or more intangibly related to a diminution in goodwill or public reputation, will be significant enough to spear a fundamental change in the way companies are willing to promote their products. Until then, however, it is important to consider other methods by which FDA can assure that the public health is being promoted and protected consistent with the goals of the FD&C Act.

Presumably, companies engage in unlawful promotion because the attendant benefits (i.e., profits) outweigh the potential risks and associated costs of such behavior. If promoting and protecting the public health are not sufficient company motivators, then efforts to pressure companies to align their behavior with the goals of the FD&C Act are necessary. If punishment, correction, and compliance efforts are not bringing about internal changes in company behavior, then pressure from external sources may be the answer. Several initiatives that focus on the receivers of information could contribute to changes in corporate behavior.

First, FDA's Office of Prescription Drug Promotion (OPDP) in the Center for Drug Evaluation and Research (CDER) should continue to promote and expand its "Bad Ad" Program.<sup>49</sup> Launched in 2010, the campaign is an "educational outreach program designed to educate healthcare providers about the role they can play in helping the agency make sure that prescription drug advertising and promotion is truthful and not misleading." The program is administered by the agency's OPDP in CDER, and has among its goals helping healthcare providers recognize misleading prescription drug promotion and providing them with an easy way to report such activity.<sup>50</sup> FDA's simple "Recognize and Report" approach to deter drug promoters from engaging in unlawful promotion is being used to create a culture of awareness among health care providers, starting at the very beginning of their careers and including medical students.<sup>51</sup> If provided with additional resources as suggested above, FDA could expand its Bad Ad Program beyond health care providers to include patients and the public generally. By providing a greater proportion of people exposed to drug information with the tools to participate in monitoring, promotion would increase the compliance pressure on companies to the benefit of the public health.

Second, in conjunction with FDA efforts to foster an environment that would engage consumers of health care information at all levels to encourage good promotional practices, Congress should continue to solicit input from interested parties about the best means of improving corporate integrity and combatting fraud. Recently, members of the Senate Committee on Finance, which has jurisdiction over Medicare and Medicaid programs, issued an open letter inviting "providers, payers, health plans, contractors, non-profit entities, consumers, data analytics entities, governmental partners, and patients" to submit solutions and suggestions for preventing and combatting



waste, fraud, and abuse in these programs.<sup>52</sup> Responses to this request may provide suggestions for expanding FDA's Bad Ad Program to increase the amount of public participation and further enhance the sense that society will not tolerate corporate behavior that puts the public health at risk.

Another measure available to increase external pressure on companies to curtail unlawful promotion is more widespread use of counter-detailing (sometimes referred to as "academic-detailing") programs, which are designed to provide health care providers with non-commercial educational information about products.<sup>53</sup> Knowing that their promotional claims are likely to be challenged and scrutinized by professionals outside the company could decrease the incentive for companies and their individual sales representatives to risk credibility by disseminating false or misleading information. Similarly, increasing the oversight role of professional associations of which companies are members might also add to the external pressure to curtail unlawful promotion. And to the extent groups like Public Citizen and the World Health Organization can influence the culture within which companies operate, their impact on compliance may be profound.<sup>54</sup> Overall, increasing awareness of promotional practices, encouraging broader participation of the public and society in general to serve as watch dogs, and fostering an environment where companies will suffer financial and other negative consequences if they are perceived as "poor corporate citizens," may very well be the ultimate tool for achieving compliance and promoting and protecting the public health.

## V. IMPACT OF POLICY RECOMMENDATIONS AND CONCLUSION

The suggested recommendations are aimed at reducing the amount of unlawful promotion that compromises the public health and the integrity of our healthcare system. When drug promotion is false or misleading, or when off-label promotion extends beyond the boundaries of truthful scientific exchange of information, safety and effectiveness are compromised and patients are at risk. DOJ settlement announcements over the past decade consistently refer to companies that "put profits over patient safety" to justify the punishments imposed.<sup>55</sup> If promotional activity is continuing to compromise the public health at the alarming rate suggested by the number and frequency of DOJ enforcement actions, then the imperative of ensuring patient safety demands that more successful compliance measures are necessary. The recommendations suggested here will further that important public health goal.

First, establishing clear guidelines about promotion that are consistent with the dissemination of truthful scientific information and that comport with the First Amendment are a crucial step toward improved compliance. By addressing companies' complaints about uncertainty and providing the specific rules necessary to design an effective compliance program, FDA can improve companies' abilities to conform their behavior to the public health goals of the FD&C Act. Second, shifting attention away from the primarily punitive enforcement efforts of the past decade and providing FDA with additional funding to expand and pursue its traditional oversight role will also better serve the public health by ensuring more timely correction and compliance and the corresponding decrease in risks to patient safety. Finally, by educating and empowering health care professionals, patients, and the public to play an active role in monitoring and reporting companies' promotional



activities, FDA and other interested groups can exert external pressure on companies that will discourage them from engaging in actions that place the public health at risk. If punishment is not achieving those goals, then efforts such as those recommended here may better protect and promote the public health as required under the FD&C Act.

## ENDNOTES

- 1 See, e.g., Press Release, U.S. Dep't of Justice, GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012), *available at* <http://www.justice.gov/opa/pr/2012/July/12-civ-842.html>.
- 2 *Friedman v. Sebelius*, 686 F.3d 813 (D.C. Cir. 2012).
- 3 21 U.S.C. §§ 321(p)(1) and 355(a) (2006).
- 4 *Id.* at § 355(b)(1).
- 5 See 21 C.F.R. 202.1(e)(4)(i)(a) (2008) (prohibiting the recommendation of a use that is not covered by the labeling in the approved new-drug application).
- 6 Michael Soares, "Off-Label" Indications for Oncology Drug Use and Drug Compendia: History and Current Status, *J. Oncology Prac.*, Sept. 2005, at 102–04.
- 7 *Id.* at 104.
- 8 See 21 C.F.R. § 201.128 (2008). Claims made in these contexts are not regulated by FDA because they fall outside the scope of the "intended use" of a drug, which refers to the objective intent of the persons legally responsible for the labeling of the product as suggested by the circumstances surrounding its distribution and marketing. *Id.*
- 9 See 21 C.F.R. § 99.101 (2008); U.S. Food & Drug Admin., Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, 2–5 (January 2008), *available at* <http://www.fda.gov/regulatoryinformation/guidances/ucm125126.htm>.
- 10 There are a number of methods by which a company, its employees, or its agents may disseminate information about off-label uses of an approved drug. See 21 C.F.R. § 99.101. The exchange of scientific information in a non-promotional context is permitted by regulation. 21 C.F.R. § 312.7(a) (2008). FDA also sanctions discussions about off-label uses in the context of industry-supported scientific and educational activities that are otherwise independent and non-promotional. See U.S. Food & Drug Admin., Guidance for Industry: Industry-Supported Scientific and Educational Activities, 2–6 (November 1997). A recent Draft Guidance addresses company responses to unsolicited requests from healthcare personnel for information about off-label uses. U.S. Food & Drug Admin., Draft Guidance for Industry: *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices* (December 2011).

- 11 See U.S. Gov't Accountability Office, Prescription Drugs: FDA's Oversight of the Promotion of Drugs for Off-Label Uses (2008) at 19 (indicating FDA did not refer any violations to the Department of Justice for enforcement between 2003 and 2007).
- 12 Among the less formal means used by FDA to achieve compliance are "untitled" or warning letters. Untitled letter offer companies the opportunity to cure misleading messages about the safe and effective use of a product. Warning letters require companies to take corrective action. See *id.* at 11. Warning Letters often include sending "Dear Doctor" letters to physicians the company has provided with questionable promotional materials in order to correct false or misleading messages about a particular product. See, e.g., Letter from Lisa M. Hubbard, Regulatory Review Officer, U.S. Food & Drug Admin., to Dennis Ahern, Assoc. Dir. of Regulatory Affairs, Shire Dev., Inc. (May 1, 2008), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm054102.pdf>.
- 13 See 2008 GAO Report, *supra* note 11 at 5 ("[T]he extent and variety of promotional activities that occur make it difficult for [the] FDA to oversee them in a *comprehensive* manner.") (emphasis added).
- 14 31 U.S.C. § 3729(a)(2006); see, e.g., Press Release, U.S. Dep't of Justice, Abbott Laboratories Sentenced for Misbranding Drug (October 2, 2012), available at <http://www.justice.gov/opa/pr/2012/October/12-civ-1195.html>.
- 15 See, e.g., *United States ex rel. Kennedy v. Aventis Pharms., Inc.*, 512 F.Supp.2d 1158, 1163 (N.D.Ill. 2007) (asserting in action under the False Claims Act that "many doctor's would not have prescribed Lovenox but for defendant's fraudulent statements"); *United States ex rel. Hess v. Sanofi-Synthelabo Inc.*, No. 4:05CV570MLM, 2006 U.S. Dist. LEXIS 22449, at \*23 (E.D. Mo. 2006) (requiring a plaintiff to plead that "but for Defendant's allegedly fraudulent misrepresentations, the doctors would not have made claims to Medicare for off-label uses" for a False Claims Act violation). For a detailed description of the application of the False Claims Act to off-label promotion see Ralph Hall & Robert Berlin, *When You Have a Hammer Everything Looks Like a Nail: Misapplication of the False Claims Act to Off-Label Promotion*, 61 Food & Drug L. J. 653 (2006).
- 16 See, e.g., Press Release, U.S. Dep't. of Justice, Justice Department Announces Largest Health Care Fraud Settlement in its History (2009) (noting that "... at the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct by its then newly acquired subsidiary, Warner-Lambert, Pfizer was itself in its other operations violating those very same laws. Today's enormous fine demonstrates that such blatant and continued disregard of the law will not be tolerated."), available at [http://www.justice.gov/usao/ma/news/Pfizer/Pfizer%20-%20PR%20\(Final\).pdf](http://www.justice.gov/usao/ma/news/Pfizer/Pfizer%20-%20PR%20(Final).pdf).
- 17 See Michael E. Clark, *The Responsible Corporate Officer Doctrine: A Re-Emergent Threat to General Counsel and Corporate Officers*, 14 J. Health Care Compliance 5 (January-February 2012).
- 18 *United States v. Park*, 421 U.S. 658 (1975).
- 19 *Id.* at 699.
- 20 42 U.S.C. § 1320a-7(b).
- 21 *Park*, 421 U.S. at 672-73.

- 22 See Ariel Glasner, *Are Misdemeanor Prosecutions Under the Park Doctrine an Effective Mechanism for Deterring Violations of the Federal Food, Drug and Cosmetic Act?*, 14 Food & Drug L. Inst. Food & Drug Policy Forum (July 26, 2011).
- 23 *Friedman v. Sebelius*, 686 F.3d 813 (D.C. Cir. 2012).
- 24 *Id.*
- 25 See Mark E. Boulding, *The Statutory Basis for FDA Regulation of Scientific and Educational Information*, 4 J. Pharmacy & L. 123, 128, 131 (1995); Office of Prescription Drug Marketing, U.S. Food & Drug Admin., Description, <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm> (last visited October 5, 2012).
- 26 Joan McPhee, *"The Criminalization of Truthful, Non-Misleading Off-Label Promotion: Constitutional, Legal and Policy Concerns,"* F-23-38 American Bar Association Health Care Fraud Conference, May 2006.
- 27 See, e.g., Complaint, *Allergan, Inc. v. United States*, No. 09-1879 (D.D.C. 2009) available at <http://druganddevicelaw.net/Allergan%20Off-label%20Complaint.pdf>; Complaint, *Par Pharmaceutical, Inc. v. United States*, 1:11-cv-01820-RWR(D.D.C. Oct. 14, 2011), available at <http://www.fuerstlaw.com/wp/wp-content/uploads/2011/10/Complaint.101411.pdf>
- 28 Citizen Petition submitted by Ropes & Gray and Sidley Austin asking FDA to clarify regulations and policies with respect to manufacturer dissemination of information relating to new uses of marketed drugs and medical devices, Docket No. FDA-2011-P-0512 (July 5, 2011).
- 29 Amicus Brief filed in *United State v. Caronia*, 09-5006-CR (2d Cir. August 22, 2011) at 1 and 15.
- 30 See 2008 GAO Report, *supra* note 11 at 19.
- 31 "The agency traditionally has recognized the important public policy reasons not to regulate all industry-supported activities as advertising or labeling. To permit industry support for the full exchange of views in scientific and educational discussions, including discussions of unapproved uses, FDA has distinguished between those activities supported by companies that are nonpromotional and otherwise independent from the substantive influence of the supporting company and those that are not. Those activities that have been deemed by the agency to be independent from influence by the supporting company and nonpromotional have not been treated as advertising or labeling, and have not been subjected to the agency's regulatory scrutiny." Guidance for Industry, *Industry-Supported Scientific and Educational Activities* (November 1997).
- 32 See Edward P. Landsdale, *Used as Directed? How Prosecutors are Expanding the False Claims Act to Police Pharmaceutical Off-Label Marketing*, 41 New Eng. L. Rev. 159, 161 (Fall 2006) (commenting on Judge Saris' decision in *United States ex. rel. Franklin v. Parke-Davis*).
- 33 Christopher D. Zalesky, *Pharmaceutical Marketing Practices: Balancing Public Health and Law Enforcement Interests; Moving Beyond Regulation Through Litigation*, 39 J. Health L. 235, 247-49 (2006).
- 34 Settlement agreements seek to achieve correction and compliance through separate Corporate Integrity Agreements. From the OIG website: "The Office of Inspector General (OIG) often negotiates compliance

- obligations with health care providers and other entities as part of the settlement of Federal health care program investigations arising under a variety of civil false claims statutes. A provider or entity consents to these obligations as part of the civil settlement and in exchange for the OIG's agreement not to seek an exclusion of that health care provider or entity from participation in Medicare, Medicaid and other Federal health care programs. . . . Providers who settle these cases often deny that they were liable or that they committed the alleged conduct." <http://www.oig.hhs.gov/fraud/cias.html> (last visited on 5/27/08). When the enforcement vehicle is the FD&C Act, the same results are achieved by Consent Decree.
- 35 See, e.g., Kevin Outterson, *Punishing Health Care Fraud—Is the GSK Settlement Sufficient?*, 367 N. Engl. J. Med. 1082 (2012).
  - 36 See, e.g., Corporate Integrity Agreement between GlaxoSmithKline and Dep't of Health & Human Services' Office of Inspector General, *available at* <http://www.justice.gov/opa/documents/gsk/plea-ex-d.pdf>.
  - 37 Press Release U.S. Dep't of Justice: International Medical Device Maker Agrees to Plead Guilty in Connection with Shipments of Adulterated and misbranded Bone Cement Products as Part of Unlawful Clinical trials (October 4, 2010), *available at* [http://www.justice.gov/usao/pae/News/2010/Oct/synthes,norian\\_release.pdf](http://www.justice.gov/usao/pae/News/2010/Oct/synthes,norian_release.pdf).
  - 38 See Sammy Almashat and Sidney Wolfe, Public Citizen Report: Pharmaceutical Industry Criminal and Civil Penalties: An Update (September 27, 2012), *available at* <http://www.citizen.org/documents/2073.pdf>.
  - 39 World Health Organization 87 Bulletin 565 (August 2009), *available at* <http://www.who.int/bulletin/volumes/87/8/09-040809/en/index.html>.
  - 40 See World Health Organization/Health Action International Collaborative Project: Understanding and Responding to Pharmaceutical Promotion, A practical Guide (First Edition 2011), *available at* <http://apps.who.int/medicinedocs/documents/s18659en/s18659en.pdf>.
  - 41 Jacqueline R. Berman, *First Amendment Off-Label Promotion Cases Work Their Way through the Courts*, 14 J. Health Care Compliance 33, 38 (March-April 2012).
  - 42 U.S. Food & Drug Admin. Draft Guidance for Industry: *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices* (December 2011).
  - 43 76 Fed. Reg. 81508 (December 28, 2011).
  - 44 See *supra*, note 27.
  - 45 Prescription Medicines Code of Practice Authority (a Division of the Association of the British Pharmaceutical Industry) (2012 2nd ed.).
  - 46 *Id.* at p. 4.
  - 47 See generally FDA Science and Mission at Risk, Report of the Subcommittee on Science and Technology to the FDA Science Board (November 2007).

- 48 Statement of Margaret A. Hamburg, FDA Commissioner before the Senate Committee on Health, Education, Labor and Pensions (July 28, 2011).
- 49 Description of FDA's Truthful Prescription Drug Advertising and Promotion (Bad Ad) Program, *available at* <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/ucm209384.htm>.
- 50 *Id.*
- 51 FDA Bad Ad Program: 2011-12 Year End Report, *available at* <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/ucm258719.htm>.
- 52 Letter from Senator Grassley and others on Health Care Reform, including solicitation of ideas on Reforms to Ensure Tougher Penalties Against Those Who Commit Fraud, *available at* <http://www.finance.senate.gov/newsroom/ranking/release/?id=d2527088-4f4c-434f-863f-5e980aaa2637>.
- 53 *See, e.g.,* <http://www.policymed.com/2011/11/ahrq-national-resource-center-for-academic-detailing.html>; Cory Andrews, *The Rise of the Pharmaceutical Un-Sales Force* (April 25, 2011), *available at* <http://www.forbes.com/sites/docket/2011/04/25/the-rise-of-the-pharmaceutical-un-sales-force/>.
- 54 *See generally* Sammy Almashat and Sidney Wolfe, Public Citizen Report: Pharmaceutical Industry Criminal and Civil Penalties: An Update (September 27, 2012), *available at* <http://www.citizen.org/documents/2073.pdf>; World Health Organization/Health Action International Collaborative Project: Understanding and Responding to Pharmaceutical Promotion, A practical Guide (First Edition 2011), *available at* <http://apps.who.int/medicinedocs/documents/s18659en/s18659en.pdf>.
- 55 *See, e.g.,* Press Release, U.S. Dep't of Justice, U.S. Pharmaceutical Company Merck Sharp & Dohme Sentenced in Connection with Unlawful Promotion of Vioxx®, *available at* <http://www.justice.gov/usao/ma/news/2012/April/MerckSentencingPR.html>.

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